

QUALITY ASSURANCE PLANNING REQUIREMENTS (QAPR) FORM INITIAL EXTRAMURAL ACTIONS

1. Choose one: ☐ Contract ☐ IAG* ☐ Simplified Acquisition
☐ Assistance Agreement ☐ CRADA*
- QA ID Number: (To be entered by QA Manager)
 - Title:
 - Does this extramural action involve the collection and/or use of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods? Check one.
☐ Yes - proceed with Step 5 ☐ No - proceed to Step 10
 - **IMPORTANT.** In order to contractually bind the awardee to the requirements delineated on this form and on the corresponding guidance documents included with this form, incorporate the following statement (verbatim) into the statement of work or special conditions:

**The awardee shall comply with all requirements as delineated on the
“Quality Assurance Planning Requirements Form” included with this extramural action.**
 - Include the “NRMRL QA Requirements/Definitions List” in the extramural documentation.
 - Check **one** of the following as applicable from Chapter 4 of the NRMRL QMP. Appropriate language must be incorporated into the solicitation and/or award/agreement documentation by CMD. If the option chosen contains “QMP,” include “Requirements for Quality Management Plans” in the extramural documentation.

The external organization shall submit:

For Competitive Extramural Actions (e.g., contract, some simplified acquisitions, some assistance agreements).	For Non-Competitive Extramural Actions (e.g., CRADAs, IAGs, some simplified acquisitions, some assistance agreements).
<input type="checkbox"/> Before Award: NRMRL's Quality System Specifications After Award: QMP and QAPP for the entire effort	(No corresponding choice)
<input type="checkbox"/> Before Award: NRMRL's Quality System Specifications After Award: Joint QMP/QAPP** for the entire effort	<input type="checkbox"/> Joint QMP/QAPP** for entire effort
<input type="checkbox"/> Before Award: NRMRL's Quality System Specifications After Award: QMP for the entire effort and a QAPP for each applicable project	<input type="checkbox"/> NRMRL's Quality System Specifications; QAPP for each applicable project
<input type="checkbox"/> Before Award: QMP for entire effort After Award: QAPP for the entire effort	<input type="checkbox"/> QMP for entire effort; QAPP for entire effort
<input type="checkbox"/> Before Award: QMP for the entire effort After Award: QAPP for each applicable project	<input type="checkbox"/> QMP for entire effort; QAPP for each applicable project
<input type="checkbox"/> Other (non-contracts):	<input type="checkbox"/> Other (non-contracts):

- Indicate in the table below all potentially applicable QAPP types that may be required at any stage of the project. Print the requirements document, and include it in the extramural action documentation.

Project Type (Choose all that apply)	Category No. (Choose from the corresponding options)
<input type="checkbox"/> Enforcement (Cat I)	Category: I
<input type="checkbox"/> Regulatory Support (Cat II)	Category: II
<input type="checkbox"/> Applied Research (Cat III)	Category: III
<input type="checkbox"/> Basic Research (Cat IV)	Category: IV
<input type="checkbox"/> Secondary Data (Cat I-IV)	Category: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
<input type="checkbox"/> Design/Construction/Operation of Environ. Technology (Cat I-IV)	Category: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
<input type="checkbox"/> Model Development (Cat I-IV)	Category: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
<input type="checkbox"/> Sampling & Analysis (Cat I-IV)	Category: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
<input type="checkbox"/> Method Development (Cat I-IV)	Category: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV
<input type="checkbox"/> Software Development & Data Management (Cat I-IV)	Category: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV

- The awardee shall comply with the following:

Quality Assurance Audits. The awardee and any subcontractor shall anticipate that one or more quality assurance audits may be performed during the project duration. These external quality assurance audits will be performed by EPA or an EPA support contractor. Selection of the specific areas of focus for audits will be commensurate with the scope and needs of the program. These external audits are intended to complement, not replace, the internal audits performed by the awardee.

Quality Assurance Reporting. Each published interim or final report produced as a result of an activity that required quality documentation shall include, as an integral section of the project report or as an Appendix, a readily identifiable discussion of the data quality of research results. Published final reports shall include the following items as a minimum:

- Discussions of the quality of data produced in terms of precision, accuracy, completeness, method detection limit, and representativeness, or semi-quantitative assessments of data quality, as applicable.
- Limitations or constraints on the use of the data, if any.

Ethics and Data Integrity. The awardee and any subcontractor shall adhere to an ethics and data integrity code. No person shall participate in:

- the intentional selective reporting of data,
- the intentional reporting of data values that are not the actual values obtained,
- the intentional reporting of dates and times of data analyses that are not the actual dates and times of data analyses, or
- the intentional representation of another's work as one's own.

Substantive Changes to EPA-Approved Quality Documentation. Any substantive changes to the specifications in the EPA-approved quality documentation shall be submitted as a revision to the quality documentation by the awardee. The awardee shall identify the change and explain the rationale for the change. The EPA TLP, in concert with the awardee, is responsible for ensuring that quality documentation is kept current. Any revisions to EPA-approved quality documentation must be submitted to the EPA TLP and the QA representative for review. Implementation of the revision(s) commence(s) only after the awardee receives written EPA approval.

10. Sign/date below, obtain QA signature, and submit with extramural action documentation.

The signatures below verify that the appropriate QA requirements have been discussed and documented on this form.

NRMRL Technical Lead Person (TLP)	Date	NRMRL QA Staff Member	Date
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*If you are processing an **IAG or CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include documentation in **IAG/CRADA** package. (Note: Documentation may partially consist of this form with the following statement in the agreement "The organizations have negotiated and agree to the requirements as delineated in the Quality Assurance Planning Requirements Form included with this IAG/CRADA package.")

**A joint QMP/QAPP, for NRMRL purposes, is the NRMRL's Quality System Specifications combined with a QAPP.